

REMARKS

Interview summary

Applicants thank Examiner Pohnert and his supervisor, Dr. Ram Shukla, for the courtesy of an interview held on March 18, 2008. Applicants have endeavored to submit this Amendment in light of the Examiner's comments during that interview.

Undersigned counsel for Applicants also wishes to apologize for the Examiner's difficulty in contacting him; however, it is respectfully noted that undersigned counsel does not recall receiving any of messages from the Examiner's office.

Status of the claims

Claims 1-5, 14-18 and 20-34 were pending in the application, with claims 1, 20 and 26 being the independent claims. Claims 20-31 are withdrawn from consideration pursuant a restriction requirement. With this submission, claims 2-3 have been canceled without prejudice or disclaimer of the subject matter therein. Claims 1, 4, 5, 14 and 16 have been amended. Thus, upon entry of this paper, claims 1, 4-5, 14-18 and 20-34 will be pending, of which claims 1, 4-5, 14-18 and 32-34 will be under active consideration.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim amendments

Claim 1 is amended to recite a single biological sample storage device for storing and testing blood or blood products, comprising a "closed" container for receiving and storing blood or blood products "for several days," comprising "a plurality" of outlets for subsequent testing of the blood or blood products. Each of the outlets comprises, in part, "an open seal situated between the container and each outlet such that the seal on each outlet can be permanently sealed from the container," "a closed seal between a first and a second section", and "a closed seal

between the second section and a third section.” Support for these amendments may be found, *inter alia*, at pages 7-9 of the original specification, Figure 1, and original claims 1-5 and 10-18.

Claim 4 is amended to recite that the closed seal between the first and second section in each outlet is a pressure sensitive seal, and that applied pressure causes the seal to break and the blood or blood product to mix with the lysis buffer or the isotonic buffer. Claim 5 is similarly amended to recite that the closed seal between the second and third section is a pressure sensitive seal, and that applied pressure causes the seal to break and the test reagents to mix with the lysed or isotonic blood or blood product. Support for these amendments may be found, *inter alia*, in paragraph [0024] at page 8 of the original specification, Figure 1, and original claims 1-5 and 10-18.

Hence, Applicants respectfully submit that these amendments do not introduce any new matter into the application and their entry is respectfully requested.

Claim rejections under 35 U.S.C. § 102

Applicants wish to thank the Examiner for indicating that the Section 102 rejection has been withdrawn.

Claim rejections under 35 U.S.C. § 103(a)

A. The rejection of claims 1-5, 14, 17-18, and 32-34

Claims 1-5, 14, 17-18 and 32-34 stand rejected under 35 U.S.C. § 103(a) as being allegedly obvious over U.S. Patent No. 4,708,850 to Husain (“Husain”) in view of WO 1999/26742 to Muir *et al* (“Muir”). The Examiner alleges, in part, that Husain teaches a blood storage and testing device with protruding outlets that may be suitably closed. Because Applicants respectfully disagree, Applicants respectfully traverse this ground of rejection.

Recent changes in the interpretation of Section 103 of the Patent Act have not disturbed the fundamental requirement that each and every element of the claimed invention be found in the prior art. *See, e.g., In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) (stating that “[a]ll words

in a claim must be considered in judging the patentability of that claim against the prior art.”) Hence, where one or more elements of a claimed invention cannot be found in or intuited from the prior art, it follows that an invention comprising one or more of such elements still cannot be rendered obvious without more. The instant invention presents such a case.

The claimed invention, as amended, is directed to a single biological sample storage device for storing and testing blood or blood products comprising a *closed* container for receiving and storing blood or blood products *for several days*; and a plurality of outlets for subsequent testing of the blood or blood products, each of the outlets comprising, in part, an open seal situated between the container and each outlet *such that the seal on each outlet can be permanently sealed from the container*. As will be next expounded, each of these elements cannot be found in the cited art.

1. The cited references, alone or in combination, fail to teach an “outlet [that] can be permanently sealed.”

Husain discloses a receptacle with a plurality of apertures, each adapted with threads that are adapted to mate respectively with threads formed around the outside of an ampule. *See, e.g.*, col. 6, ln. 47-52 and 66-68. As shown in Figures 1 and 2, absent a respective ampule, each aperture is merely an unsealed opening. Once an ampule is fitted to its corresponding aperture, the aperture becomes “closed,” as defined by Husain. Figures 1 and 4 depict such “closed” apertures.

As best shown in Figure 4, however, even the “closed” apertures remain “open” and accessible for fluid—namely, blood—to freely traverse into and out of the ampules from the receptacle. In other words, there is no seal, let alone a permanent seal, situated between the receptacle and each aperture. *See, e.g.*, blood sample 58 in Figures 4 and 5.

By contrast, the presently claimed invention *does* comprise such as seal. *See, e.g.*, seal #1 (32) in Figure 1. The seal enables a first section of the plurality of outlets to be permanently sealed off from the closed container. It follows that once sealed, blood or blood products held in the first section can no longer mix with and contaminate blood or blood products in the

container. This feature and advantage is not found in the device of Husain. Muir does not cure this deficiency.

2. The cited references, alone or in combination, fail to teach a “closed” container.

Husain discloses a receptacle for determining the blood type of a donor or patient according to the ABO classification system. Col. 1, first paragraph. Husain’s device is equipped with an open “mouth,” which is not sealed, and given the perishable nature of blood and blood products, precludes the long term storage of blood or blood products within the receptacle. Indeed, the device is inherently a single-use device, because a blood sample must be allowed to react within an anti-A serum ampule, an anti-B serum ampule, *and* an anti-Rh serum ampule at substantially the same time for an accurate determination of blood type. Once the sera have been used—*i.e.*, once the determination of blood type has been made—the receptacle can no longer support another test.

The claimed invention, in contrast, comprises a container for storing blood or blood products “for several days.” Consequently, the container is a “closed” container. Being “closed,” the container also prevents contamination of the blood or blood products, which enables controlled, “subsequent” testing of the blood or blood products over a span of several days.

These features and advantages are not found in the device of Husain, and Muir does not cure these deficiencies. Taken together, therefore, insofar as the prior art fails to disclose the noted elements of the claimed invention, it remains that a *prima facie* case for obviousness cannot be properly established. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. The rejection of claims 15 and 16

Claims 15 and 16 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Husain in view of Muir and further in view of U.S. Patent No. 5,589,332 to Shih *et al.* ("Shih"). Applicants respectfully traverse this rejection on the following grounds.

As noted above, where one or more elements of a claimed invention cannot be found in or intuited from the prior art, an invention comprising one or more of such elements cannot be rendered obvious without more. In the present case, even assuming, *arguendo*, that Shih discloses the use of a ribozyme as a diagnostic tool to detect the presence a nucleic acid in a solution, the reference fails to teach a *closed* container for receiving and storing blood or blood products *for several days*; and a plurality of outlets for subsequent testing of the blood or blood products, each outlet comprising, in part, an open seal situated between the container and each outlet *such that the seal on each outlet can be permanently sealed from the container*. Thus, Shih, like Muir, fails to cure the deficiency of the primary reference Husain.

For at least these reasons, the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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